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ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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May 10, 2019

Mr. Thomas Moriarty
Executive Vice President
Chief Policy and External Affairs Officer
General Counsel
CVS Health
1 CVS Drive
Woonsocket, Rhode Island 02895

Dear Mr. Moriarty:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, April 10, 2019, at the hearing entitled "Priced out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin." We appreciate the time and effort you gave as a witness before the Subcommittee on Oversight and Investigations.

Pursuant to Rule 3 of the Committee on Energy and Commerce, members are permitted to submit additional questions to the witnesses for their responses, which will be included in the hearing record. Attached are questions directed to you from members of the Committee. In preparing your answers to these questions, please address your responses to the member who has submitted the questions using the Word document provided with this letter.

To facilitate the publication of the hearing record, please submit your responses to these questions by no later than the close of business on Friday, May 24, 2019. As previously noted, this transmittal letter and your responses, as well as the responses from the other witnesses appearing at the hearing, will all be included in the hearing record. Your responses should be transmitted by e-mail in the Word document provided with this letter to Jourdan Lewis, Policy Analyst with the Committee, at jourdan.lewis@mail.house.gov. You do not need to send a paper copy of your responses to the Committee. Using the Word document provided for submitting your responses will also help maintain the proper format for incorporating your answers into the hearing record.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Ms. Lewis at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Chairman

Attachments

cc: Hon. Greg Walden, Ranking Member
Committee on Energy and Commerce

Hon. Diana DeGette, Chair
Subcommittee on Oversight and Investigations

Hon. Brett Guthrie, Ranking Member
Subcommittee on Oversight and Investigations

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin"
April 10, 2019

Mr. Thomas Moriarty, Executive Vice President,
Chief Policy and External Affairs Officer, and General Counsel
CVS Health

The Honorable Joseph P. Kennedy III (D-MA)

1. Last year, CVS Caremark sent a letter regarding the 340B program to various pharmacies in Massachusetts stating that CVS Caremark would be reducing reimbursement rates. Please provide a list of all pharmacies to which CVS Caremark sent this letter.

2. It is my understanding CVS Caremark has since rescinded its proposal to reduce reimbursement rates to pharmacies owned by safety net providers. What caused CVS Caremark to change course? Will CVS Caremark commit to refrain from similar anticompetitive tactics undermining the 340B program in the future?

3. How would the reduction in reimbursement rates affect medication adherence for diabetic patients if CVS Caremark put it in place? How would the reduction in reimbursement rates affect access to insulin?

The Honorable Brett Guthrie (R-KY)

1. In December 2018, CVS Health announced that it was introducing a new approach to pricing of pharmacy benefit management services, referred to the Guaranteed Net Cost Model. Will the Guaranteed Net Cost Model apply to all insulin products?

    a. What percentage of CVS Caremark's clients have chosen to adopt the new model? What is CVS Caremark doing, if anything, to incentivize clients to adopt this model?

    b. According to press releases, CVS Health will pass through 100 percent of rebates in the Guaranteed Net Cost Model. Why under the traditional rebate model does CVS Health only pass through 98 percent of the rebates? How will CVS Health be compensated under the Guaranteed Net Cost model? Will the amount CVS Health receives be a fixed fee or will it vary depending on different factors?

    c. One article notes that a CVS spokesperson said that "the company does not expect CVS Health's profitability to increase or decrease as a result of the shift to 100%

pass-through rebates."[1] Is this correct? If so, please explain why a shift to 100 percent pass-through of rebates will not impact CVS Health's profitability.

d. Under the Guaranteed Net Cost Model, will CVS Health share information about the price of the medicine paid by CVS Health to obtain a medicine such as insulin with its clients?

e. What impact, if any, will the Guaranteed Net Cost Model have on the out-of-pocket costs for a patient at the pharmacy counter—especially those patients that are in the deductible phase of a high deductible health plan or that have coinsurance for their insulin?

2. We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. Manufacturers have said that they oftentimes increase list prices to provide greater rebates and obtain formulary placement for their product. On the other hand, we have heard from many Pharmacy Benefit Managers (PBMs), including CVS Health, that PBMs typically prefer the product with the lowest net price when there are competing products available—such as generic medicines or therapeutically equivalent alternatives. It therefore is not clear why manufacturers continue to increase the list price of insulin and provide greater rebates for these products rather than simply reducing the list price.

To help us better understand the role of rebates, there is a hypothetical question below.

> There are two therapeutically equivalent insulin products, product A and product B. Product A has a list price of $100 and CVS Health is offered a rebate of 50 percent, thereby making the final price to CVS Health's client $50. Product B has a list price of $50, and CVS Health is not offered any rebates for the product.

a. Is there any reason CVS Health would prefer Product A, the product with the higher list price and rebate, over Product B? If so, please describe.

b. Which drug would be more profitable for CVS Health to include on the formulary?

c. How does CVS Health determine the "net price" of the medicine?

d. How would CVS Health decide which product to include on formulary or would CVS Health include both products on its formulary?

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[1] Evan Sweeney, *CVS Caremark shifts PBM model to 100% pass-through pricing and focus on net cost*, FIERCE HEALTHCARE (Dec. 5, 2018), *available at* https://www.fiercehealthcare.com/payer/cvs-caremark-launches-guaranteed-pbm-model-100-pass-through-pricing.

e. My understanding is that pharmacy benefit managers (PBMs) have generally provided their clients with guaranteed levels of rebates, and in some instances, if the PBM exceeds the guarantee level, they may keep all or some of those rebates.

   i. During the last 5 years, how many times has CVS Health exceeded the level of rebates that it guaranteed to its clients? How much did CVS Health retain as a result?

   ii. What happens if CVS Health does not achieve this guaranteed level of rebates?

3. What factors does CVS Health consider when deciding whether to include an authorized generic on its formulary?

   a. In CVS Health's experience, how many manufacturers making an authorized generic refuse to provide a rebate that would make the net price of the authorized generic less than the brand drug?

   b. If CVS Health does get a lower net price on the authorized generic and put it on formulary, will CVS Health keep the branded product on formulary as well? Why?

   c. Has CVS Health ever gotten a lower net price on an authorized generic and put it on its formulary and kept the branded product on formulary as well? If so, why?

4. There have been press reports about a letter that one Pharmacy Benefit Manager (PBM), OptumRx, sent to pharmaceutical manufacturers requesting that pharmaceutical manufacturers provide the PBM with notice if the manufacturer decides to lower the list price of a medicine. Has CVS Health sent a similar letter to pharmaceutical manufacturers and/or does CVS Health require that manufacturers provide the company with advance notice of a list price decrease? If yes:

   a. Please describe the terms of this requirement and when CVS Health established this requirement.

   b. If a pharmaceutical manufacturer does not provide CVS Health with sufficient notice that the manufacturer will decrease the list price of a medicine, what will the manufacturer's rebate liability be for the product in each market (*e.g.*, commercial, Medicare Part D, etc.)?

   c. Have any manufacturers reduced the list price of insulin without giving CVS Health sufficient notice and triggered this provision?

5. During the hearing, the witnesses were asked about administrative fees paid by manufacturers to PBMs and how these administrative fees are oftentimes a percentage of the wholesale acquisition cost (WAC)—or list price—of a medicine.

a. What are the advantages and disadvantages of having administrative fees that are a percentage of the WAC, or list price, of a medicine?

b. Does your company support moving to a system where administrative fees are based on a flat fee instead?

6. During the hearing, pharmaceutical manufacturers testified that one reason pharmaceutical companies have increased their list prices is because the companies had to provide larger rebates to have their product included on formularies and maintain formulary access and access to patients. If manufacturers lowered the list price of their medicines and therefore provided lower rebates to PBMs, would your company continue to offer the same formulary access that you are offering to pharmaceutical manufacturers at higher list prices? In your opinion, if insulin products had lower list prices and lower rebates as a result, would the use of exclusive formularies increase or decrease?

The Honorable Michael C. Burgess (R-TX)

1. One thing that has constantly come up in our conversations about drug pricing is that high deductible plans have become increasingly common. When did high-deductible health plans start to become more common?

2. As enrollment in high deductible health plans has grown, patients have been increasingly exposed to higher out-of-pocket costs for medicines. We've heard that some PBMs have recommended that their clients include insulin on preventive drug lists, which would result in there being first-dollar coverage of insulin for beneficiaries in high deductible health plans.

    a. What kinds of drugs are commonly included on preventive drug lists?

3. One chart from Express Scripts' 2018 Drug Trend Report shows that the out-of-pocket cost for patients in a high-deductible plan per 30 day adjusted Rx in 2018 was $40.69 when insulin was on a preventive drug list, compared to $105.16 when insulin was not on a preventive drug list. Given preventive medications can help people avoid many illnesses and conditions, and the aforementioned chart shows that having a drug, such as insulin, on a preventive drug list can save the patient money – do each of you have data that shows the savings to the patient as well as the overall health care system as a result of having a medication, such as insulin, on a preventive drug list?

    a. CVS told the Committee that you encourage clients who use health savings accounts (HSAs) to cover preventive drugs with a $0 copay and prior to satisfaction of the deductible. Additionally, since CVS Health provides its employees with an HSA plan, CVS said it covers certain preventive drugs and supplies with a $0 copay and prior to satisfaction of the deductible. Does CVS provide insulin to its employees with an HSA plan with a $0 copay and prior to satisfaction of the deductible? Why or why not?

i. We've heard that some plans have the option of taking insulin out of the deductible entirely for enrollees in a high deductible health plan. Do you offer this to your clients and, if so, do you recommend that your clients include insulin on their preventive drug lists for high deductible health plans?

ii. How long have you recommended that your clients include insulin on their preventive drug list?

iii. Do you know how many of your clients use preventative drug lists, and have insulin on their preventive list? What percentage of your clients is that?

iv. How many covered lives does that translate to?

4. What are some of the reasons why a client wouldn't use a preventive list and include insulin on that list?

The Honorable Jeff Duncan (R-SC)

1. One thing that we heard from patients and doctors last week is that insulin hasn't changed much, so they don't understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba and Fiasp and have also created new, more accurate and convenient delivery systems. Further, Sanofi noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.

   Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx's testimony stated that "[i]nsulin has been used to treat diabetes for nearly 100 years, and "manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents."

   So, which is it? Is there innovation in the insulin market or not?

2. One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product."

   Yet, OptumRx's testimony states that "[f]or years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."

So, which is it? Are there patents preventing innovation and competition or not?

3. As follow-up to that, we have specifically heard concerns about patent "evergreening," which is when brand-name companies patent a slight modification of an older drug. Some say that evergreening does not significantly improve the therapeutic nature of the drug, but rather it provides the company that made the drug an economic advantage by avoiding more competition entering the market.

   In your opinion, do these patent "evergreening" concerns apply to the insulin products themselves or does it more so have to do with the newer delivery devices?

   a. If a company wants to create a generic alternative or biosimilar version of an insulin pen product, what are the existing regulatory barriers that make it difficult for them to create the generic alternative if there are only patents remaining on the delivery device?

   b. If the delivery device is the only part of the product that is patented, why aren't we at least seeing generic versions of insulin vials?